

8 July 2024

Original: English

(24-4976) Page: 1/4

Committee on Sanitary and Phytosanitary Measures

NOTIFICATION

1. Notifying Member: <u>UNITED KINGDOM</u>

If applicable, name of local government involved:

- **2. Agency responsible:** The United Kingdom (UK) Food Safety Authorities comprising of the Food Standards Agency (FSA) and Food Standards Scotland (FSS)
- 3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):

Four novel foods:

- RP200 cetylated fatty acids (new authorisation)
- RP19 Partially hydrolysed protein from spent barley (*Hordeum vulgare*) and rice (*Oryza sativa* (new authorisation)
- RP549 lacto-*N*-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) (new authorisation)
- RP1202 3-fucosyllactose (3-FL) (produced by a derivative strain of Escherichia coli K-12 DH1) (new authorisation)

Three food additives:

- RP1084 Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts (new production method of an existing authorised food additive)
- RP1140 Steviol Glycosides (E 960b) produced by Yarrowia lipolytica (new production method of an existing authorised food additive)
- RP217 Polyglycerol polyricinoleate (PGPR, E 476) (extension of use of an authorised food additive)

Twenty-two flavouring substances:

- 1-(4-Methoxyphenyl)pent-1-en-3-one (FL No 07.030) (removal)
- Vanillylidene acetone (FL No 07.046) (removal)
- 1-(4-Methoxyphenyl)-4-methylpent-1-en-3-one (FL No 07.049) (removal)
- 4-(2,3,6-Trimethylphenyl)but-3-en-2-one (FL No 07.206) (removal)
- 6-Methyl-3-hepten-2-one (FL No 07.258) (removal)
- 5,6-Dihydro-3,6-dimethyl-benzofuran-2(4H)-one (FL No 10.034) (removal)
- 5,6,7,7a-Tetrahydro-3,6-dimethylbenzofuran-2(4H)-one (FL No 10.036) (removal)
- 3,4-Dimethyl-5-pentylidene-furan-2(5H)-one (FL No 10.042) (removal)
- 2,7-Dimethylocta-5(trans),7-dieno-1,4-lactone (FL No 10.043) (removal)
- Hex-2-eno-1,4-lactone (FL No 10.046) (removal)
- Non-2-eno-1,4-lactone (FL No 10.054) (removal)
- 2-Decen-1,4-lactone (FL No 10.060) (removal)
- 5-Pentyl-3H-furan-2-one (FL No 10.170) (removal)
- Allyl 2-furoate (FL No 13.004) (removal)
- 3-(2-furyl)acrylaldehyde (FL No 13.034) (removal)
- Furfurylidene-2-butanal (FL No 13.043) (removal)
- 4-(2-Furyl)but-3-en-2-one (FL No 13.044) (removal)
- 3-(2-Furyl)-2-methylprop-2-enal (FL No 13.046) (removal)
- 3-Acetyl-2,5-dimethylfuran (FL No 13.066) (removal)
- 2-Butylfuran (FL No 13.103) (removal)
- 3-(2-Furyl)-2-phenylprop-2-enal (FL No 13.137) (removal)
- 3-(5-Methyl-2-furyl)prop-2-enal (FL No 13.150) (removal)

- 4. Regions or countries likely to be affected, to the extent relevant or practicable:
 - [X] All trading partners
 - [] Specific regions or countries:
- **5. Title of the notified document:** Authorisation of four novel foods, new production method for two food additives, an extension of use of an authorised food additive, a new limit for ethylene oxide in all food additives and the removal of twenty-two flavouring substances. **Language(s):** English. **Number of pages:** 25 (England), 27 (Scotland), 27 (Wales)

Full text of the legislation is linked for:

England: https://www.legislation.gov.uk/uksi/2024/685/introduction/made
Scotland: https://www.legislation.gov.uk/ssi/2024/156/contents/made
Wales: https://www.legislation.gov.uk/wsi/2024/741/contents/made

6. **Description of content:** The United Kingdom intends to authorise four novel foods and three food additives (two new production methods and one extension of use of an existing authorisation). The United Kingdom also intends to set a limit for ethylene oxide in all food additives replacing the current outright prohibition, a clear limit that provides clarity and consistency to industry and enforcers, facilitating trade. The United Kingdom is also making various minor and technical amendments to the list of authorised novel foods and food additives to correct identified errors and omissions, including the removal of twenty-two food flavouring authorisations in Great Britain (GB) that are no longer in use.

The new authorisations are:

Novel foods:

- **Cetylated fatty acids (new authorisation)**. The authorisation is for a new application to use cetylated fatty acids within the food category: food supplements for the general population.
- Partially hydrolysed protein from spent barley (Hordeum vulgare) and rice
 (Oryza sativa (new authorisation). The authorisation is for food categories
 including: bakery products, breakfast cereals, spreadable fats and dressings, grain
 products and pastas, snack foods, jam, marmalade and other fruit spreads,
 candy/confectionery, dairy and dairy imitates, dessert sauces and syrups, meat
 imitates, soups and soup mixes, savoury sauces, legume-based spreads, nut-based
 spreads, energy drinks, foods and beverages intended for sportspersons and meal
 replacements for weight control.
- Lacto-N-fucopentaose I (LNFP-I) and 2'-fucosyllactose (2'-FL) (new authorisation). The new authorisation is for LNFP-I/2'-FL in dairy products and analogues, bakery wares, beverages, foods for infants and young children, foods for special medical purposes, total diet replacement for weight control, and food supplements.
- 3-fucosyllactose (produced by a derivative strain of *Escherichia coli* K-12 DH1) (new authorisation). The new authorisation is to use the novel food within the following food categories: dairy products and analogues, bakery wares, foods for special groups, beverages, and as a food supplement.

Food additives:

- Rebaudioside M, AM and D produced via enzymatic conversion of highly purified steviol glycosides from stevia leaf extracts (new production method of an existing authorised food additive). It would be used in food and beverages as a high-intensity sweetener for the replacement of sucrose in reduced-calorie or nosugar-added products.
- Steviol Glycosides (E 960b) produced by Yarrowia lipolytica (new production method of an existing authorised food additive). Used in jams, chewing gum, drinks, yoghurts, and confectionery. It is also available in pure form for use in tea, coffee, and baking.
- Polyglycerol polyricinoleate (PGPR, E 476) (extension of use of an existing authorised food additive). Polyglycerol polyricinoleate (PGPR, E 476) is an emulsifier made from polyglycerol and fatty acids. This extension of use allows this food additive in ice creams and frozen yogurts and at a higher level in certain types of

sauces. This is an extension of use of the already authorised additive polyglycerol polyricinoleate (PGPR, E 476) to allow use in 'Edible Ices', with the restriction 'except sorbets'.

• Ethylene oxide (amendment): Ethylene oxides is already prohibited from being used as a sterilising agent for all food additives. It is however used as a raw material in the manufacture for some food additives. Ethylene oxide is classified as carcinogenic, mutagenic and toxic for reproduction. The FSA/FSS have conducted rapid risk assessments in relation to various incidents involving additives (xanthan gum, guar gum, locust bean gum and calcium carbonate) where ethylene oxide or its breakdown product 2-chloroethanol was detected. An amendment is required to the Annex to assimilated Regulation No 231/2012 to set a maximum limit at what is deemed to be a level that can be consistently quantified (0.1mg/kg). This facilitates trade as currently any finding of ethylene oxide is prohibited. Setting a maximum limit at 0.1mg/kg means any finding below that would be tolerated and the additive can be placed on the market.

Food Flavourings:

• Removal of authorisation of twenty-two 'flavouring substances under evaluation' from the GB approved list. The flavourings industry requested their deletion from the list and will not submit any of the additional information required to complete the evaluation. They will be removed from the list set out in Annex I of assimilated Regulation 1334/2008. This is unlikely to affect trade as the international flavouring trade associations have said these flavourings are no longer used in food. The legislation contains transitional measures for foods exported to GB in case there were any legacy uses, prior to the producers withdrawing their support for these flavourings.

Further information can be found in the consultations linked in section 9.

- 7. Objective and rationale: [X] food safety, [] animal health, [] plant protection, [] protect humans from animal/plant pest or disease, [] protect territory from other damage from pests.
- 8. Is there a relevant international standard? If so, identify the standard:
 - [X] Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): CXG-62-2007 Working Principles for Risk Analysis for Food Safety for Application by Governments
 - [] World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):
 - [] International Plant Protection Convention (e.g. ISPM number):
 - [] None

Does this proposed regulation conform to the relevant international standard?

[X] Yes [] No

If no, describe, whenever possible, how and why it deviates from the international standard:

9. Other relevant documents and language(s) in which these are available: Full details of the applications for authorisation or removal of these regulated products are laid out in the public consultations and safety assessments on the FSA and FSS websites available here:

FSA Consultation FSS Consultation (available in English)

10. Proposed date of adoption (dd/mm/yy): 28 June 2024

Proposed date of publication (dd/mm/yy): 28 June 2024

11. Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): 28 June 2024

[X] Trade facilitating measure

12. Final date for comments: [] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable

Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Department for Environment, Food and Rural Affairs

Seacole Building 2 Marsham St London SW1P 4DF

E-mail: uksps@defra.gov.uk

Website: https://www.gov.uk/government/organisations/department-for-environment-

food-rural-affairs

13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

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